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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC. Defendants.	Civil Action No. 23-cv-20964-JXN-MAH **JURY TRIAL DEMANDED**

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC; AMNEAL IRELAND LIMITED; AMNEAL PHARMACEUTICALS LLC; and AMNEAL PHARMACEUTICALS INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Defendants Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; and Amneal Pharmaceuticals Inc. (collectively, "Defendants"), by and through their undersigned counsel, for their Answer to the First Amended Complaint filed by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs"), and their Counterclaims against Plaintiffs, hereby state as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in Plaintiffs' First Amended Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) ("Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 211600 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol prior to the expiration of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent"). Collectively, the '712 patent, the '289 patent, the '587 patent, the '808 patent, and the '889 patent are referred to herein as the "Patents-in-Suit."

ANSWER: Amneal admits that Counts I, III, V, VII, and IX of the First Amended Complaint purport to state causes of action for patent infringement under 35 U.S.C. § 271(e).

Amneal admits that Counts II, IV, VI, VIII, and X of the First Amended Complaint purport to state causes of action under the Declaratory Judgment Act for alleged potential patent infringement under 35 U.S.C. § 271(a). Amneal admits that this action arises out of one or more of the Plaintiffs having improperly caused the "Patents-in-Suit" to become listed for ProAir® HFA (albuterol sulfate) Inhalation Aerosol in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), Amneal's subsequent submission of ANDA No. 211600 ("Amneal's ANDA") seeking FDA approval to market Amneal's generic version of ProAir® HFA prior to expiration of the Patents-in-Suit, and Plaintiffs' decision to sue Defendants within 45 days after receiving notice of Amneal's Paragraph IV filing, triggering a 30-month stay of final FDA approval of Amneal's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Amneal denies the remaining allegations in paragraph 1.

THE PARTIES

Plaintiffs

2. Plaintiff Teva Branded is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

ANSWER: On information and belief, admitted.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, *i.e.*, does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

ANSWER: On information and belief, admitted.

4. Plaintiff Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER: On information and belief, admitted.

Defendants

5. On information and belief, Defendant Amneal NY is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal NY is a wholly-owned subsidiary of Amneal Pharma. On further information and belief, Amneal NY is the U.S. agent for Amneal Ireland.

ANSWER: Admitted.

6. On information and belief, Defendant Amneal Ireland is a company organized and existing under the laws of Ireland, having a place of business at Cahir Road, Cashel, Co. Tipperary, Ireland E25 XD5l.

ANSWER: Admitted.

7. On information and belief, Defendant Amneal Pharma is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal Pharma is a wholly-owned subsidiary of Amneal Inc.

ANSWER: Admitted.

8. On information and belief, Defendant Amneal Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400

Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

ANSWER: Admitted.

9. On information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this District. *See* Amneal Pharmaceuticals, Inc., Form 10-K for 2022 Fiscal Year, at 6-8 https://s22.q4cdn.com/186279204/files/doc_financials/2023/07/Amneal-2022-Form-10-K-asfiled.pdf (last visited October 6, 2023).

ANSWER: Admitted.

10. By a letter dated August 24, 2023 ("Amneal Notice Letter"), Defendant Amneal NY notified Plaintiffs that Amneal NY and Amneal Ireland had submitted to FDA Amneal's ANDA for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg per actuation ("Amneal ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amneal ANDA Products in and/or into the United States, including New Jersey, prior to the expiration of the Patents-in-Suit.

ANSWER: Admitted.

11. On information and belief, Defendants acted in concert to prepare and submit Amneal's ANDA and the Amneal Notice Letter.

ANSWER: Denied.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

ANSWER: Defendants incorporate each of its answers to preceding paragraphs 1–11 as if fully set forth herein.

13. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271.

ANSWER: Defendants incorporate their answer to paragraph 1 as if set forth herein.

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Denied.

Personal Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1–14 as if fully set forth herein.

ANSWER: Defendants incorporate each of its answers to preceding paragraphs 1–14 as if fully set forth herein.

16. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Defendants.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 16 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

17. This Court has personal jurisdiction over Defendants because, among other things, Defendants have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. On information and belief, Defendants develop, manufacture, import, market, offer to sell, sell, and/or import generic drugs throughout the United States, including in New Jersey, and therefore transact business within New Jersey, and/or have engaged in systematic and continuous business contacts within New Jersey.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 17 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

18. In addition, this Court has personal jurisdiction over Defendants because, among other things, on information and belief: (1) Defendants filed Amneal's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products in the United States, including in New Jersey; and (2) upon approval of Amneal's ANDA, Defendants, individually and/or in concert, will market, distribute, offer for sale, sell, and/or import the Amneal ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Amneal ANDA Products in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Amneal's ANDA, the Amneal ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 18 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

19. On information and belief, this Court also has personal jurisdiction over Defendant Amneal Inc. because it has its principal place of business in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 19 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court, and Defendants admit that Amneal, Inc. has a principal place of business in New Jersey. Otherwise denied.

20. On information and belief, this Court also has personal jurisdiction over Defendant Amneal Pharma because it has its principal place of business in New Jersey.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 20 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court, and Defendants admit that Amneal Pharma has a principal place of business in New Jersey. Otherwise denied.

21. On information and belief, this Court also has personal jurisdiction over Defendant Amneal NY because it has its principal place of business in New Jersey.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 21 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court, and Defendants admit that Amneal NY has a principal place of business in New Jersey. Otherwise denied.

22. On information and belief, this Court also has personal jurisdiction over Defendant

Amneal Ireland because its U.S. agent, Amneal NY, has its principal place of business in New Jersey. On information and belief, Amneal Ireland acts through its U.S. agent Amneal NY.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 22 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court, and Defendants admit that Amneal NY has a principal place of business in New Jersey. Otherwise denied.

23. The Amneal Notice Letter was sent by Bryan Sommese, Esq., Senior Patent Litigation Counsel – IP, for Amneal Pharma in Bridgewater, New Jersey, on behalf of Amneal NY and Amneal Ireland.

ANSWER: Defendants admit that the Amneal Notice Letter was signed by Bryan Sommese, Esq., Senior Patent Litigation Counsel – IP, for Amneal Pharmaceuticals of New York. Otherwise denied.

24. On information and belief, one or more acts related to Amneal's preparation of Amneal's ANDA were conducted in this District and/or will be conducted in the District.

ANSWER: Admitted.

25. On information and belief, Defendant Amneal Inc.'s corporate headquarters is located in Bridgewater, New Jersey.

ANSWER: Admitted.

26. On information and belief, Defendant Amneal NY is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003663, originally issued on October 7, 2008.

ANSWER: Admitted.

27. On information and belief, Defendant Amneal Pharma is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5002991, originally issued on April 3, 2003. The Registered Addresses include 131 Chambers Brook Rd., Branchburg, NJ 08876; 1 New England Ave, Piscataway, NJ 08854; 1 Murray Rd, East Hanover, NJ 07936; 19 Readington Rd., Branchburg, NJ 08876; 47 Colonial Dr., Piscataway, NJ 08854; 21 Colonial Dr., Piscataway, NJ 08854; 400 Crossing Blvd., 3rd Fl., Bridgewater, NJ 08807; and 65 Readington Rd., Branchburg, NJ 08876.

ANSWER: Admitted as to Amneal Pharmaceuticals LLC. Otherwise denied.

28. On information and belief, Defendant Amneal Pharma is registered with the State of New Jersey's Department of the Treasury, Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600211542.

ANSWER: Admitted as to Amneal Pharmaceuticals LLC. Otherwise denied.

29. On information and belief, Defendant Amneal Pharma leases at least ten (10) significant properties in New Jersey for the purposes of its executive offices, R&D, manufacturing, packaging, and warehousing, including in Bridgewater, Piscataway, Branchburg, and East Hanover. *See* Amneal Pharmaceuticals, Inc., Form 10-K for 2022 Fiscal Year, at 46 https://s22.q4cdn.com/186279204/files/doc_financials/2023/07/Amneal-2022-Form-10-K-as-filed.pdf (last visited October 6, 2023).

ANSWER: Admitted that Amneal Pharmaceutical, Inc. leases ten properties in New Jersey that are identified on the cited page of the cited Form 10-K as "significant properties," and that the "Purpose" listed on the cited page of the cited Form 10-K for at least one of those properties is "Executive Office," "Warehouse," "Manufacturing," "Packaging," and "R&D." Admitted that as of the time of the preparation of this answer, the cited Form 10-K was available at the cited web

address. Defendants lack information sufficient to form a belief as to when Plaintiffs "last visited" that web address, and on that basis deny such allegation. Otherwise denied.

30. In addition, this Court has personal jurisdiction over Defendants Amneal Ireland and Amneal NY because, on information and belief, Amneal NY, the U.S. agent of Amneal Ireland, regularly (1) engages in patent litigation concerning its ANDA Products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See*, *e.g.*, Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (not contesting personal jurisdiction in this District and asserting counterclaims); Answer (Dkt. 14) ¶¶ 20, 26, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW- CLW (D.N.J. filed March 4, 2019) ("Amneal admits that Amneal NY has not contested personal jurisdiction in this District in several previous matters, solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 30 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

31. In addition, this Court has personal jurisdiction over Defendant Amneal Pharma because, on information and belief, Amneal Pharma regularly (1) engages in patent litigation concerning its ANDA Products in this District; (2) does not contest personal jurisdiction in this

District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv-05256-FLW- TJB (D.N.J. filed July 7, 2020) (not contesting personal jurisdiction in this District and asserting counterclaims); Answer (Dkt. 14) ¶ 16, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) ("Amneal LLC admits that it has not contested personal jurisdiction in this District in several previous matters solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv- 05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 31 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

32. In addition, this Court has personal jurisdiction over Defendant Amneal Inc. because, on information and belief, Amneal Inc., directly or indirectly through its subsidiaries including Amneal Pharma and Amneal NY, regularly (1) engages in patent litigation concerning its ANDA Products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See* Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (Amneal Inc. not contesting personal jurisdiction in this District and asserting counterclaims); *see also, e.g.*, Answer (Dkt. 14) ¶ 16, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et*

al., No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) ("Amneal LLC admits that it has not contested personal jurisdiction in this District in several previous matters solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv- 05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 32 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

33. For the above reasons, it would not be unfair or unreasonable for Defendants to litigate this action in this District, and the Court has personal jurisdiction over Defendants here.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 33 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Defendants deny the allegation that it would not be unfair or unreasonable for Defendants to litigate this action. Otherwise denied.

34. In the alternative, Defendant Amneal Ireland is subject to personal jurisdiction in this forum because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Amneal Ireland is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Amneal Ireland has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Amneal's ANDA, and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, including in this District, such that this Court's exercise of jurisdiction over Amneal Ireland satisfies due

process.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 34 is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Otherwise denied.

Venue

35. Plaintiffs incorporate each of the preceding paragraphs 1–34 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–34 as if fully set forth herein.

36. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 36 is required, for purposes of this action only, Defendants do not contest venue in this Judicial District. Otherwise denied.

37. On information and belief, Defendants have a regular and established place of business in this District and have committed and/or will commit acts of infringement in this District. *See* 28 U.S.C. § 1400(b).

ANSWER: Denied.

38. On information and belief, Defendants have committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit by, among other things, preparing or assisting in preparing Amneal's ANDA in New Jersey and/or seeking to market the Amneal ANDA Products throughout the United States, including within New Jersey.

ANSWER: Denied.

39. On information and belief, Defendants (1) engage in patent litigation concerning their ANDA Products in this District, and (2) do not contest venue in this District. *See, e.g.*, Answer (Dkt. 11) ¶ 39, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv- 05256-FLW-TJB (D.N.J. filed July 7, 2020) (Amneal Inc., Amneal Pharma, and Amneal NY, the U.S. agent of Amneal Ireland, not contesting that venue is proper in this District); Answer (Dkt. 14) ¶¶ 59, 60, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv- 17585-WHW-CLW (D.N.J. filed March 4, 2019) (Amneal Pharma and Amneal NY, the U.S. agent of Amneal Ireland, not contesting venue in this District); Answer (Dkt. 87) ¶ 143, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) (same).

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 39 is required, for purposes of this action only, Defendants do not contest venue in this District. Defendants admit that at least some of the Defendants have engaged in patent litigation in this District without contesting venue. Otherwise denied.

40. On information and belief, Defendant Amneal Inc. has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal NY, Amneal Ireland, and Amneal Pharma to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers

or distributors providing for the distribution of Defendants' products in the State of New Jersey.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 40 is required, for purposes of this action only, Defendants do not contest venue in this District. Otherwise denied.

41. On information and belief, Defendant Amneal Pharma has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal NY, Amneal Ireland, and Amneal Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 41 is required, for purposes of this action only, Defendants do not contest venue in this District. Otherwise denied.

42. On information and belief, Defendant Amneal NY has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal Ireland, Amneal Pharma, and Amneal Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving

substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 42 is required, for purposes of this action only, Defendants do not contest venue in this District. Otherwise denied.

43. On information and belief, Defendant Amneal Ireland has a regular and established place of business in this District at least because it: (1) has acted in concert with Amneal NY, Amneal Pharma, and Amneal Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (2) conducts business, individually and/or in concert with its U.S. agent, Amneal NY that is located in the State of New Jersey, in this District; and (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 43 is required, for purposes of this action only, Defendants do not contest venue in this District. Otherwise denied.

44. Venue is also proper in this District for Amneal Ireland at least because, among other things, Amneal Ireland is a foreign corporation organized and existing under the laws of Ireland and may be sued in any judicial district in which it is subject to personal jurisdiction, including in the State of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer to paragraph 44 is required, for purposes of this action only, Defendants do not contest venue in this District. Otherwise denied.

BACKGROUND

NDA No. 021457

45. Teva Branded is the holder of New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir® HFA (albuterol sulfate) Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

ANSWER: On information and belief, admitted.

46. On October 1, 2022, the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued. Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

The '712 Patent

47. The '712 patent, titled "Metered-Dose Inhaler," duly and legally issued on March 13, 2012. A true and correct copy of the '712 patent is attached hereto as Exhibit A.

ANSWER: Defendants admit that the '712 patent bears the title "Metered-Dose Inhaler." Defendants admit that the '712 patent bears an issue date of March 13, 2012. Defendants admit that there was an Exhibit A attached to the First Amended Complaint and that Exhibit A appears to be a copy of the '712 patent. Otherwise denied.

48. Norton is the owner and assignee of the '712 patent.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

49. The '712 patent is listed in connection with ProAir® HFA (NDA No. 021457) in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ANSWER: Admitted.

50. The Orange Book currently lists the expiration of the '712 patent as September 7, 2028.

ANSWER: Admitted.

The '289 Patent

51. The '289 patent, titled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof," duly and legally issued on October 11, 2016. A true and correct copy of the '289 patent is attached hereto as Exhibit B.

ANSWER: Defendants admit that the '289 patent bears the title "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof." Defendants admit that the '289 patent bears an issue date of October 11, 2016. Defendants admit that there was an Exhibit B attached to the First Amended Complaint and that Exhibit B appears to be a copy of the '289 patent. Otherwise denied.

52. Norton is the owner and assignee of the '289 patent.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

53. The '289 patent is listed in connection with ProAir® HFA (NDA No. 021457) in

the Orange Book.

ANSWER: Admitted.

54. The Orange Book currently lists the expiration of the ’289 patent as May 18, 2031.

ANSWER: Admitted.

The ’587 Patent

55. The ’587 patent, titled “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator,” duly and legally issued on November 7, 2017. A true and correct copy of the ’587 patent is attached hereto as Exhibit C.

ANSWER: Defendants admit that the ’587 patent bears the title “Dose Counters for Inhaler Having an Anti-Reverse Rotation Actuator.” Defendants admit that the ’587 patent bears an issue date of November 7, 2017. Defendants admit that there was an Exhibit C attached to the First Amended Complaint and that Exhibit C appears to be a copy of the ’587 patent. Otherwise denied.

56. Norton is the owner and assignee of the ’587 patent.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

57. The ’587 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Admitted.

58. The Orange Book currently lists the expiration of the ’587 patent as May 18, 2031.

ANSWER: Admitted.

The ’808 Patent

59. The ’808 patent, titled “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator,” duly and legally issued on February 18, 2020. A true and correct copy of the ’808 patent is attached hereto as Exhibit D.

ANSWER: Defendants admit that the ’808 patent bears the title “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator.” Defendants admit that the ’808 patent bears an issue date of February 18, 2020. Defendants admit that there was an Exhibit D attached to the First Amended Complaint and that Exhibit D appears to be a copy of the ’808 patent. Otherwise denied.

60. Norton is the owner and assignee of the ’808 patent.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

61. The ’808 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Admitted.

62. The Orange Book currently lists the expiration of the ’808 patent as January 1, 2032.

ANSWER: Admitted.

The ’889 Patent

63. The ’889 patent, titled “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator,” duly and legally issued on July 26, 2022. A true and correct copy of the ’889 patent is attached hereto as Exhibit E.

ANSWER: Defendants admit that the '889 patent bears the title "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator." Defendants admit that the '889 patent bears an issue date of July 26, 2022. Defendants admit that there was an Exhibit E attached to the First Amended Complaint and that Exhibit E appears to be a copy of the '889 patent. Otherwise denied.

64. Norton is the owner and assignee of the '889 patent.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of this allegation, and on that basis deny same.

65. The '889 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Admitted.

66. The Orange Book currently lists the expiration of the '889 patent as May 18, 2031.

ANSWER: Admitted.

Defendants' ANDA and Notice of Paragraph IV Certification

67. On information and belief, Defendants have submitted or caused the submission of Amneal's ANDA to FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Amneal ANDA Products prior to the expiration of the Patents-in-Suit.

ANSWER: Admitted.

68. On information and belief, FDA has not yet approved Amneal's ANDA.

ANSWER: Admitted.

69. In the Amneal Notice Letter, Defendant Amneal NY notified Plaintiffs of the

submission of Amneal's ANDA to FDA.

ANSWER: Admitted.

70. In the Amneal Notice Letter, Defendant Amneal NY notified Plaintiffs that Amneal had filed a Paragraph IV Certification with respect to each of the Patents-in-Suit and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Patents-in- Suit.

ANSWER: Admitted.

71. The purpose of Defendants' submission of Amneal's ANDA to FDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Patents-in-Suit.

ANSWER: Admitted.

72. On information and belief, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Amneal's ANDA, and intend to further prosecute Amneal's ANDA. On information and belief, if FDA approves Amneal's ANDA, Defendants will manufacture, offer for sale, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States. On information and belief, if FDA approves Amneal's ANDA, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Products in or into the United States.

ANSWER: Admitted.

73. In the Amneal Notice Letter, Defendant Amneal NY stated that the subject of Amneal's ANDA is "Albuterol Sulfate Inhalation Aerosol, 90 mcg per actuation."

ANSWER: Admitted.

74. In the Amneal Notice Letter, Defendant Amneal NY stated that the active ingredient of the Amneal ANDA Products is albuterol sulfate.

ANSWER: Admitted.

75. In the Amneal Notice Letter, Defendant Amneal NY stated that the dosage form of the Amneal ANDA Products is "inhalation aerosol."

ANSWER: Admitted.

76. In the Amneal Notice Letter, Defendant Amneal NY stated that the strength of the Amneal ANDA Products is 90 mcg per actuation.

ANSWER: Admitted.

77. On information and belief, Amneal's ANDA contains a Paragraph IV Certification with respect to each of the Patents-in-Suit asserting that the Patents-in-Suit are unenforceable, invalid, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Products ("Amneal's Paragraph IV Certification"). Defendants notified Plaintiffs of Amneal's Paragraph IV Certification in the Amneal Notice Letter, dated August 24, 2023, sent by United Parcel Service.

ANSWER: Admitted.

78. In the Amneal Notice Letter, Defendants offered Plaintiffs confidential access to ANDA No. 211600 on terms and conditions set forth in an attached "Offer of Confidential Access"

("OCA"). The OCA provided by Defendants contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

ANSWER: Defendants admit that in the Amneal Notice Letter, Defendants offered Plaintiffs confidential access to ANDA No. 211600 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). Defendants admit that the OCA provided by Defendants contained various terms and conditions. Otherwise denied.

79. By correspondence, counsel for Plaintiffs and counsel for Defendants discussed the terms of Defendants' OCA.

ANSWER: Admitted.

80. On September 16, 2023, Plaintiffs' counsel sent Defendants' counsel an email identifying various unreasonably restrictive terms in Defendants' OCA. Plaintiffs' counsel also included a revised draft of the OCA in this correspondence.

ANSWER: Defendants admit that Plaintiffs' counsel sent Defendants' counsel an email on September 16, 2023 providing a revised OCA. Otherwise denied.

81. On September 25, 2023, Defendants' counsel sent Plaintiffs' counsel a revised OCA. That offer addressed some of Plaintiffs' concerns but remained unreasonably restrictive.

ANSWER: Defendants admit that Defendants' counsel sent Plaintiffs' counsel a further revised OCA on September 25, 2023. Otherwise denied.

82. On September 27, 2023, Plaintiffs' counsel sent another email reiterating its concerns regarding the restrictions in Defendants' OCA, and attaching a revised draft of the OCA.

ANSWER: Defendants admit that on September 27, 2023, Plaintiffs' counsel sent another email to Defendants' counsel attaching a further revised draft of the OCA. Otherwise denied.

83. On September 28, 2023, the parties reached agreement on the terms of the OCA, which was finalized on October 2, 2023. Amneal did not produce any portion of its ANDA until October 3, 2023 and did not produce the requested samples until October 4, 2023, shortly before the 45-day statutory deadline to file suit.

ANSWER: Defendants admit that the parties reached agreement on the terms of the OCA on September 28, 2023, that the OCA was finalized on October 2, 2023, that Defendants produced its ANDA on October 3, 2023 and produced samples on October 4, 2023. Otherwise denied.

84. The Amneal Notice Letter appends a document titled "Detailed Factual and Legal Basis of Non-Infringement, Unenforceability, and/or Invalidity" asserting that the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Products will not infringe any of the Patents-in-Suit ("Detailed Statement"). However, the Amneal Notice Letter and "Detailed Statement" do not provide information regarding the Amneal ANDA Products sufficient to evaluate Defendants' assertions of noninfringement.

ANSWER: Defendants admit that the Amneal Notice Letter appends a document titled "Detailed Factual and Legal Basis of Non-Infringement, Unenforceability, and/or Invalidity" asserting that the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Products will not infringe any of the Patents-in-Suit ("Detailed Statement"). Otherwise denied.

85. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C.

§ 355(j)(5)(B)(iii), the timing of the production of Amneal's ANDA and samples, and the limited information provided by Defendants to date, Plaintiffs turn to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that the Amneal ANDA Products fall within the scope of one or more claims of the Patents-in-Suit.

ANSWER: Defendants deny that the purpose for which Plaintiffs "turn to the judicial process" is as stated in paragraph 85. Defendants lack information sufficient to form a belief as to remaining allegations of paragraph 85 and on that basis deny same.

86. This action was commenced within 45 days from the date of Plaintiffs' receipt of the Amneal Notice Letter.

ANSWER: Admitted.

COUNT I – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,132,712 UNDER 35 U.S.C. § 271(E)(2)

87. Plaintiffs incorporate each of the preceding paragraphs 1–86 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–86 as if fully set forth herein.

88. Amneal's submission of Amneal's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the '712 patent was an act of infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

89. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '712 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Denied.

90. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '712 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

91. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '712 patent.

ANSWER: Denied.

92. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 92, and deny them on that basis.

93. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '712 patent, including at least claim 1.

ANSWER: Denied.

94. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '712 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

95. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '712 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '712 patent after approval of Amneal's ANDA.

ANSWER: Denied.

96. The foregoing actions by Amneal constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Denied.

97. On information and belief, Amneal has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Denied.

98. Unless Amneal is enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,132,712

99. Plaintiffs incorporate each of the preceding paragraphs 1–98 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–98 as if fully set forth herein.

100. Amneal has knowledge of the '712 patent.

ANSWER: Admitted.

101. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '712 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

102. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 102, and deny them on that basis.

103. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '712 patent, including at least claim 1.

ANSWER: Denied.

104. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '712 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

105. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '712 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '712 patent after approval of Amneal's ANDA.

ANSWER: Denied.

106. The foregoing actions by Amneal constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Denied.

107. On information and belief, Amneal has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Denied.

108. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling

according to Amneal's ANDA will infringe one or more claims of the '712 patent, including at least claim 1, and whether said claims of the '712 patent are valid.

ANSWER: Denied.

109. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '712 patent and that the claims of the '712 patent are valid.

ANSWER: Denied.

110. Amneal should be enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT III – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,463,289 UNDER 35 U.S.C. § 271(E)(2)

111. Plaintiffs incorporate each of the preceding paragraphs 1–110 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–110 as if fully set forth herein.

112. Amneal's submission of Amneal's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the '289 patent was an act of infringement of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

113. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '289 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Denied.

114. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '289 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

115. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '289 patent.

ANSWER: Denied.

116. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 116, and deny them on that basis.

117. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '289 patent, including at least claim 1.

ANSWER: Denied.

118. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the ’289 patent when Amneal’s ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

119. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the ’289 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the ’289 patent after approval of Amneal’s ANDA.

ANSWER: Denied.

120. The foregoing actions by Amneal constitute and/or will constitute infringement of the ’289 patent, active inducement of infringement of the ’289 patent, and contribution to the infringement by others of the ’289 patent.

ANSWER: Denied.

121. On information and belief, Amneal has acted with full knowledge of the ’289 patent and without a reasonable basis for believing that it would not be liable for infringing the ’289 patent, actively inducing infringement of the ’289 patent, and contributing to the infringement by others of the ’289 patent.

ANSWER: Denied.

122. Unless Amneal is enjoined from infringing the ’289 patent, actively inducing

infringement of the ’289 patent, and contributing to the infringement by others of the ’289 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,463,289

123. Plaintiffs incorporate each of the preceding paragraphs 1–122 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–122 as if fully set forth herein.

124. Amneal has knowledge of the ’289 patent.

ANSWER: Admitted.

125. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the ’289 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

126. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal’s ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 126, and deny them on that basis.

127. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal’s proposed labeling for those products would infringe one or more

claims of the ’289 patent, including at least claim 1.

ANSWER: Denied.

128. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the ’289 patent when Amneal’s ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

129. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the ’289 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the ’289 patent after approval of Amneal’s ANDA.

ANSWER: Denied.

130. The foregoing actions by Amneal constitute and/or will constitute infringement of the ’289 patent, active inducement of infringement of the ’289 patent, and contribution to the infringement by others of the ’289 patent.

ANSWER: Denied.

131. On information and belief, Amneal has acted with full knowledge of the ’289 patent and without a reasonable basis for believing that it would not be liable for infringing the ’289 patent, actively inducing infringement of the ’289 patent, and contributing to the infringement by others of the ’289 patent.

ANSWER: Denied.

132. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal's ANDA will infringe one or more claims of the '289 patent, including at least claim 1, and whether said claims of the '289 patent are valid.

ANSWER: Denied.

133. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '289 patent and that the claims of the '289 patent are valid.

ANSWER: Denied.

134. Amneal should be enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT V – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,808,587 UNDER 35 U.S.C. § 271(E)(2)

135. Plaintiffs incorporate each of the preceding paragraphs 1–134 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–134 as if fully set forth herein.

136. Amneal's submission of Amneal's ANDA for the purpose of obtaining approval to

engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the '587 patent was an act of infringement of the '587 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

137. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '587 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Denied.

138. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '587 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

139. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '587 patent.

ANSWER: Denied.

140. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 140, and deny them on that basis.

141. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '587 patent, including at least claim 1.

ANSWER: Denied.

142. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '587 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

143. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '587 patent after approval of Amneal's ANDA.

ANSWER: Denied.

144. The foregoing actions by Amneal constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

ANSWER: Denied.

145. On information and belief, Amneal has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

ANSWER: Denied.

146. Unless Amneal is enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,808,587

147. Plaintiffs incorporate each of the preceding paragraphs 1–146 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–146 as if fully set forth herein.

148. Amneal has knowledge of the '587 patent.

ANSWER: Admitted.

149. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '587 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

150. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 150, and deny them on that basis.

151. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '587 patent, including at least claim 1.

ANSWER: Denied.

152. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '587 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

153. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '587 patent after approval of Amneal's ANDA.

ANSWER: Denied.

154. The foregoing actions by Amneal constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

ANSWER: Denied.

155. On information and belief, Amneal has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

ANSWER: Denied.

156. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal's ANDA will infringe one or more claims of the '587 patent, including at least claim 1, and whether said claims of the '587 patent are valid.

ANSWER: Denied.

157. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '587 patent and that the claims of the '587 patent are valid.

ANSWER: Denied.

158. Amneal should be enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VII – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,561,808 UNDER 35 U.S.C. § 271(E)(2)

159. Plaintiffs incorporate each of the preceding paragraphs 1–158 as if fully set forth herein.

ANSWER: Defendants incorporate each of the preceding paragraphs 1–158 as if fully set forth herein.

160. Amneal's submission of Amneal's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the '808 patent was an act of infringement of the '808 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

161. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Denied.

162. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '808 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

163. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '808 patent.

ANSWER: Denied.

164. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 164, and deny them on that basis.

165. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '808 patent, including at least claim 1.

ANSWER: Denied.

166. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '808 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

167. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '808 patent after approval of Amneal's ANDA.

ANSWER: Denied.

168. The foregoing actions by Amneal constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Denied.

169. On information and belief, Amneal has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Denied.

170. Unless Amneal is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,561,808

171. Plaintiffs incorporate each of the preceding paragraphs 1–170 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–170 as if fully set forth herein.

172. Amneal has knowledge of the '808 patent.

ANSWER: Admitted.

173. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '808 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

174. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 174, and deny them on that basis.

175. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '808 patent, including at least claim 1.

ANSWER: Denied.

176. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '808 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

177. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '808 patent after approval of Amneal's ANDA.

ANSWER: Denied.

178. The foregoing actions by Amneal constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Denied.

179. On information and belief, Amneal has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Denied.

180. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal's ANDA will infringe one or more claims of the '808 patent, including at least claim 1, and whether said claims of the '808 patent are valid.

ANSWER: Denied.

181. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

ANSWER: Denied.

182. Amneal should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT IX – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 11,395,889 UNDER 35 U.S.C. § 271(E)(2)

183. Plaintiffs incorporate each of the preceding paragraphs 1–182 as if fully set forth herein.

ANSWER: Defendants incorporate each of the preceding paragraphs 1–182 as if fully set forth herein.

184. Amneal's submission of Amneal's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the '889 patent was an act of infringement of the '889 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

185. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '889 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Denied.

186. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '889 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

187. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '889 patent.

ANSWER: Denied.

188. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 188, and deny them on that basis.

189. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '889 patent, including at least claim 1.

ANSWER: Denied.

190. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '889 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

191. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '889 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '889 patent after approval of Amneal's ANDA.

ANSWER: Denied.

192. The foregoing actions by Amneal constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Denied.

193. On information and belief, Amneal has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Denied.

194. Unless Amneal is enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 11,395,889

195. Plaintiffs incorporate each of the preceding paragraphs 1–194 as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1–194 as if fully set forth herein.

196. Amneal has knowledge of the '889 patent.

ANSWER: Admitted.

197. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products would infringe one or more claims of the '889 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

198. On information and belief, Amneal will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Amneal ANDA Products immediately and imminently upon FDA approval of Amneal's ANDA.

ANSWER: Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 188, and deny them on that basis.

199. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal's proposed labeling for those products would infringe one or more claims of the '889 patent, including at least claim 1.

ANSWER: Denied.

200. On information and belief, Amneal plans and intends to, and will, actively induce infringement of the '889 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

201. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '889 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '889 patent after approval of Amneal's ANDA.

ANSWER: Denied.

202. The foregoing actions by Amneal constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Denied.

203. On information and belief, Amneal has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Denied.

204. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal's ANDA will infringe one or more claims of the '889 patent, including at least claim 1, and whether said claims of the '889 patent are valid.

ANSWER: Denied.

205. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '889 patent and that the claims of the '889 patent are valid.

ANSWER: Denied.

206. Amneal should be enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to the judgement or any of the relief requested in Plaintiffs' Prayer for Relief or otherwise.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the First Amended Complaint not otherwise admitted. Defendants reserve the right to assert additional defenses, at law or in equity, as they become known through further investigation and discovery. Defendants do not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs have failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Lack of Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction.

THIRD AFFIRMATIVE DEFENSE
(Non-infringement of the '712 patent)

The filing of ANDA No. 211600 has not infringed and does not infringe any valid and enforceable claim of the '712 patent. Moreover, the manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 211600 has not and will not infringe any valid or enforceable claims of the '712 patent either directly or indirectly, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of the '712 patent)

The claims of the '712 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Non-infringement of the '289 patent)

The filing of ANDA No. 211600 has not infringed and does not infringe any valid and enforceable claim of the '289 patent. Moreover, the manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 211600 has not and will not infringe any valid or enforceable claims of the '289 patent either directly or indirectly, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of the '289 patent)

The claims of the '289 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE
(Non-infringement of the '587 patent)

The filing of ANDA No. 211600 has not infringed and does not infringe any valid and enforceable claim of the '587 patent. Moreover, the manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 211600 has not and will not infringe any valid or enforceable claims of the '587 patent either directly or indirectly, either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of the '587 patent)

The claims of the '587 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Non-infringement of the '808 patent)

The filing of ANDA No. 211600 has not infringed and does not infringe any valid and enforceable claim of the '808 patent. Moreover, the manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 211600 has not and will not infringe any valid or enforceable claims of the '808 patent either directly or indirectly, either literally or under the doctrine of equivalents.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of the '808 patent)

The claims of the '808 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and obviousness-type double patenting.

ELEVENTH AFFIRMATIVE DEFENSE
(Non-infringement of the '889 patent)

The filing of ANDA No. 211600 has not infringed and does not infringe any valid and enforceable claim of the '889 patent. Moreover, the manufacture, use, sale, and/or offer for sale of the proposed generic products that are the subject of ANDA No. 211600 has not and will not infringe any valid or enforceable claims of the '889 patent either directly or indirectly, either literally or under the doctrine of equivalents.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of the '889 patent)

The claims of the '889 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and obviousness-type double patenting.

THIRTEENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

Plaintiffs are barred from obtaining the relief they seek because Plaintiffs have unclean hands.

FOURTEENTH AFFIRMATIVE DEFENSE
(Patent Misuse)

U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent") (collectively, the "Asserted Patents") are unenforceable because Plaintiffs have engaged in misuse of the Asserted Patents by seeking to impermissibly broaden the scope of the patent grant with respect to the Asserted Patents, with anticompetitive effect.

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COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant/Counterclaim-Plaintiff Amneal Pharmaceuticals LLC ("Amneal"), by and through its counsel, alleges the following counterclaims against Plaintiffs/Counterclaim-Defendants Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Counterclaim-Defendants") based on personal knowledge, the investigation of counsel, and information and belief.

NATURE OF THE ACTION

1. Amneal repeats and incorporates by reference each of the foregoing paragraphs 1–206 of its Answer as well as its Affirmative Defenses to the First Amended Complaint, as if fully set forth herein.

2. These counterclaims seek a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent") (collectively, the "Asserted Patents"); removal of the Asserted Patents from the Orange Book listing for ProAir® HFA, under 28 U.S.C. §§ 2201, 2202, and 21 U.S.C. § 355(j)(5)(C)(ii)(I); and relief from Counterclaim-Defendants' anticompetitive conduct to insulate, extend, and protect their monopoly in the market for ProAir® HFA and its generic equivalents, in violation of state and federal antitrust laws.

3. Upon information and belief, a true and correct copy of the '712 patent was attached to Plaintiff's First Amended Complaint as Exhibit A, a true and correct copy of the '289 patent was attached to Plaintiff's First Amended Complaint as Exhibit B, a true and correct copy of the '587 patent was attached to Plaintiff's First Amended Complaint as Exhibit C, a true and

correct copy of the '808 patent was attached to Plaintiff's First Amended Complaint as Exhibit D, and a true and correct copy of the '889 patent was attached to Plaintiff's First Amended Complaint as Exhibit E.

PARTIES

4. Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

5. Upon information and belief, Counterclaim-Defendant Teva Branded is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

6. Upon information and belief, Counterclaim-Defendant Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, *i.e.*, does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

7. Upon information and belief, Counterclaim-Defendant Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

8. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and 21 U.S.C. § 355(j)(5)(C)(ii)(I). These counterclaims are also instituted under the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys'

fee, for the injuries sustained by Amneal resulting from violations by Counterclaim-Defendants, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2.

9. This Court has subject matter jurisdiction to hear these counterclaims under 28 U.S.C. §§ 1331, 1337(a), and 1338(a); 15 U.S.C. §§ 15 and 26; and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The Court has jurisdiction over the state law claims under 28 U.S.C. § 1367(a).

10. This Court has personal jurisdiction over Counterclaim-Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint and First Amended Complaint here.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), and because Counterclaim-Defendants commenced this lawsuit in this venue.

12. There is an actual and justiciable controversy between the parties that is of sufficient immediacy and reality to warrant the relief sought in these counterclaims.

BACKGROUND

A. AMNEAL'S ANDA AND THE 30-MONTH STAY OF FDA APPROVAL OF AMNEAL'S ANDA THAT COUNTERCLAIM-DEFENDANTS TRIGGERED BY BRINGING THEIR BASELESS PATENT LITIGATION

13. On information and belief, Counterclaim-Defendant Teva Branded is the holder of New Drug Application ("NDA") No. 21-457 ("ProAir® NDA"), under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol.

14. On information and belief, Counterclaim-Defendants listed and maintained a listing for the Asserted Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 021457.

15. The Asserted Patents do not meet the statutory requirements to be listed in the Orange Book, as they do not claim a drug, drug substance (active ingredient), drug product (formulation or composition), or a method of using a drug. *See* 21 U.S.C. § 355(b)(1)(A)(viii).

16. Amneal Pharmaceuticals of NY, LLC ("Amneal NY") and Amneal Ireland Ltd. ("Amneal Ireland") submitted Abbreviated New Drug Application ("ANDA") No. 211600 ("Amneal's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Albuterol Sulfate HFA Inhalation Aerosol, 90 mcg per actuation ("Amneal ANDA Products").

17. Amneal NY is a direct subsidiary of Amneal Pharmaceuticals LLC, and Amneal Ireland is an indirect subsidiary of Amneal Pharmaceuticals LLC.

18. Because Counterclaim-Defendants had improperly listed the Asserted Patents in the Orange Book, and because Amneal NY and Amneal Ireland sought approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ProAir® HFA prior to the expiration of the Asserted Patents, Amneal NY and Amneal Ireland were required to file a Paragraph IV Certification with respect to each of the Asserted Patents. A Paragraph IV Certification certifies that a patent listed in the Orange Book is invalid or will not be infringed by the manufacture, use or sale of the ANDA product.

19. In accordance with 21 U.S.C. §355 (j)(2)(B)(iv)(II), by letter dated August 24, 2023 ("Amneal Notice Letter"), Amneal NY notified Counterclaim-Defendants that Amneal NY and Amneal Ireland had submitted to the FDA Amneal's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

20. On information and belief, Counterclaim-Defendants received the Amneal Notice Letter on August 28, 2023.

21. Counterclaim-Defendants filed this lawsuit on October 6, 2023, claiming that Amneal has infringed and will infringe the Asserted Patents by the filing of Amneal's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the products described in that ANDA.

22. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Amneal are objectively baseless. As described below, no reasonable litigant could expect to secure favorable relief against Amneal on the merits because the Amneal ANDA Products does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid.

23. Counterclaim-Defendants filed this lawsuit within 45 days of receiving the Amneal Notice Letter. By doing so, Counterclaim-Defendants triggered a 30-month stay of final FDA approval of Amneal's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay, which is imposed only where an NDA holder files a patent infringement suit within 45 days of receiving notice of a Paragraph IV certification, is not set to expire until February 28, 2026 – long after Amneal expects, based on FDA correspondence to Amneal, being otherwise able to launch the Amneal ANDA Products.

24. But for Counterclaim-Defendants' improper listing of the Asserted Patents in the Orange Book and Counterclaim-Defendants' choice to bring baseless litigation within 45 days of receipt of the Amneal Notice Letter, there would be no 30-month stay imposed under 21 U.S.C. § 355(j)(5)(B)(iii).

25. During the time between the summer of 2024, when Amneal expects final approval, and February 28, 2026, Amneal will be deprived of the ability to launch its generic product, and consumers be deprived of the benefits of lower-priced generic competition from Amneal.

B. PATENT LISTING AND THE ORANGE BOOK

26. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

27. Pursuant to the FDCA, any company that wishes to sell a new drug in the United States must seek FDA approval by filing an NDA with the FDA. As part of that application, the submitter of the NDA must provide the FDA with information identifying each patent "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" that is the subject of the NDA, and that either (I) "claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent;" or (II) "claims a method of using such drug for which approval is sought or has been granted in the application." 21 U.S.C. § 355(b)(1)(A)(viii); *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC.*, 60 F.4th 1373, 1377 (Fed. Cir. 2023).

28. Submission of information on patents that do not meet these criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

29. Upon approval of an NDA, the patent information submitted to the FDA by the NDA holder under 21 U.S.C. § 355(b)(1)(A)(viii) is published by the FDA in a publicly-available online database entitled "Approved Drug Products with Therapeutic Equivalence

Evaluations | Orange Book" (the "Orange Book"). *Jazz Pharms., Inc.*, 60 F.4th at 1377. The Orange Book is located at the following web address: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

30. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *Jazz Pharms., Inc.*, 60 F.4th at 1378. Rather, the FDA's role with respect to Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting FDA arguments that (i) FDA does not have a duty to determine "whether the patent claims the drug," (ii) "FDA has a only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharmaceuticals, Inc.*, 60 F.4th at 1378.

31. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

C. APPROVAL OF GENERIC DRUGS

32. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a "Paragraph I Certification."

33. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a "Paragraph IV Certification" or "PIV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

34. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

35. If the ANDA contains Paragraph III Certifications and no PIV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. §355 (j)(5)(B)(ii).

36. If an ANDA contains one or more PIV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. §355 (j)(2)(B)(iv)(II).

37. If an ANDA containing a PIV Certification is the first such ANDA submitted, then, subject to other requirements, it can qualify for 180 days of generic exclusivity, during which the FDA will not make effective its approval of another ANDA product that is a generic version of the same NDA product as the first-to-file ANDA. 21 U.S.C. §355 (j)(5)(B)(iv).

38. The filing of a PIV Certification is treated under the patent law as an act of technical infringement that provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement suit within 45 days after it receives the notice of the PIV filing, the FDA's approval of the corresponding ANDA will

automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. §355 (j)(5)(B)(iii).

39. If an infringement action is brought against an ANDA applicant in response to receiving notice of a PIV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

D. THE PROAIR® HFA NDA AND PRODUCT

40. ProAir® HFA was approved under the ProAir® NDA.

41. The ProAir® NDA was submitted by Ivax Research, Inc. ("Ivax") to the FDA on January 31, 2003.

42. The ProAir® NDA was approved by FDA on October 29, 2004.

43. Attached as Exhibit A is a copy of the FDA approval letter reflecting the submission and approval dates for the ProAir® NDA.

44. At the time of its approval on October 29, 2004, there was no approved trade name for the product that was the subject of NDA No. 21-457.

45. The trade name originally proposed for the product that was the subject of NDA No. 21-457 was Volare HFA (Albuterol Sulfate, USP) Inhalation Aerosol. The FDA did not approve of that trade name for the product that was the subject of NDA No. 21-457.

46. Attached as Exhibit B is a copy of the collection of "Administrative Documents/Correspondence" for NDA No. 21-457 published by the FDA, reflecting the originally proposed trade name on the final page.

47. Attached as Exhibit C is a copy of the labeling for NDA No. 21-457 approved on October 29, 2004.

48. The ProAir® NDA was submitted under Section 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984, and relied on Proventil HFA Inhalation Aerosol as the comparator drug.

49. Attached as Exhibit D is a copy of the Medical Review from the Approval Package for the ProAir® NDA. On at least page three, it reflects the 505(b)(2) status of the ProAir® NDA and identifies Proventil HFA Inhalation Aerosol as the comparator drug.

50. The ingredients in ProAir® HFA are albuterol sulfate, propellant HFA-134a, and ethanol. The active ingredient in ProAir® HFA is albuterol sulfate. Attached as Exhibit E is a copy of the current Prescribing Information and Patient Information for ProAir® HFA.

51. As reflected in the ProAir® HFA label, albuterol sulfate was first approved by FDA more than forty years ago, in 1981. *See* Exhibit E (ProAir® HFA Prescribing Information at page 1).

52. ProAir® HFA was initially approved without a dose counter. Attached as Exhibit D is a copy of the Medical Review from the ProAir® NDA Approval Package. Page three of this exhibit, which is internal page 2 of the Division Director's Memorandum of October 29, 2004, states: "A dose counter is not included in this drug product. This will be addressed by the applicant in future submissions."

53. The Prescribing Information and Patient Information for ProAir® HFA has been amended several times since its initial approval in 2004. Attached as Exhibit F is a copy of the list published by the FDA of the Approval Dates and History, Letters, Labels, and Reviews for the ProAir® NDA.

54. On August 17, 2010, in connection with a Supplemental New Drug Application to the ProAir® NDA, the FDA approved a revised package insert and patient instructions for use in

support of an actuator approved on September 22, 2009. Attached as Exhibit G is a copy of the August 17, 2010 Supplement Approval letter from the FDA reflecting this approval.

55. The earliest approved Prescribing Information and Patient Information for ProAir® HFA reflecting the presence of a dose counter attached to the actuator is the March 2012 revision. Attached as Exhibit H is a copy of the March 2012 revision of the Prescribing Information and Patient Information for ProAir® HFA.

56. The March 2012 revision of the Prescribing Information and Patient Information for ProAir® HFA replaced the July 2010 revision. The July 2010 revision of the Prescribing Information and Patient Information for ProAir® HFA does not refer to a dose counter. Attached as Exhibit I is a copy of the July 2010 revision of the Prescribing Information and Patient Information for ProAir® HFA.

57. ProAir® HFA is approved for treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm in patients 4 years of age and older.

58. On information and belief, Counterclaim-Defendants discontinued marketing ProAir® HFA in October 2022, but continue to sell an authorized generic version of the product.

E. PRIOR ANDAS FOR GENERIC PROAIR® HFA

59. Counterclaim-Defendants Teva Branded and Norton, together with Teva Respiratory, LLC and Norton Healthcare Limited, have established a pattern and practice of improperly listing device patents in the Orange Book and subsequently asserting those device patents against ANDA filers seeking to market generic versions of ProAir® HFA within 45 days of the filing of any Paragraph IV Certification thereto, thereby ensuring the ANDA applicant's approval is subject to the automatic 30-month stay.

60. On September 5, 2012, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited, filed a lawsuit captioned *Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited v. Perrigo Pharmaceuticals Co., Perrigo Co., and Catalent Pharma Solutions, LLC*, U.S. District Court for the District of Delaware, Case 1:12-cv-01101 (defendants collectively "Perrigo"). Teva asserted U.S. Patent Nos. 7,105,152 ("the '152 patent") and 7,566,445 ("the '445 patent") in their complaint against Perrigo. The '445 patent is a device patent that Teva improperly listed in the Orange Book. On information and belief, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited filed a lawsuit against Perrigo within the 45-day period prescribed by 21 U.S.C. § 355(j)(5)(B)(iii), thereby triggering a 30-month stay of FDA approval of Perrigo's ANDA. The lawsuit was resolved by means of a stipulated dismissal on June 20, 2014.

61. On March 21, 2017, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited, filed a lawsuit captioned *Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited v. Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd.*, U.S. District Court for the District of Delaware, Case 1:17-cv-00307 (defendants collectively "Lupin"). Teva asserted U.S. Patent Nos. 7,105,152 ("the '152 patent"), 8,132,712 ("the '712 patent"), and 9,463,289 ("the '289 patent") in the complaint against Lupin. The '712 and '289 patents are device patents that Teva improperly listed in the Orange Book, and that Counterclaim-Defendants asserted in the First Amended Complaint against Amneal in the present case. On information and belief, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited filed their

lawsuit within the 45-day period prescribed by 21 U.S.C. § 355(j)(5)(B)(iii), thereby triggering a 30-month stay of FDA approval of Lupin's ANDA. This lawsuit against Lupin was resolved by means of a stipulated dismissal on November 2, 2017.

62. These two prior lawsuits demonstrate that Counterclaim-Defendants Teva Branded and Norton, together with Teva Respiratory, LLC and Norton Healthcare Limited, have engaged in enforcement efforts relating to device patents listed improperly in the Orange Book for ProAir® HFA to try to delay or stop generic market entry.

63. According to the FDA, the date of first commercial marketing of a generic version of ProAir® HFA by the first-to-file ANDA applicant was February 26, 2020. Attached as Exhibit J is a copy of the Paragraph IV Patent Certifications published by the FDA and dated October 16, 2023. Page two of that document contains the entry for ProAir® HFA and reflects the February 26, 2020 launch date of the first-to-file generic version of ProAir® HFA.

64. More than 180 days have elapsed since February 26, 2020.

65. Currently, there is no ANDA applicant eligible for 180-day generic exclusivity, and any such exclusivity that may once have existed has expired or has been extinguished. Accordingly, there is no barrier to removal of the Asserted Patents from the Orange Book pursuant to 21 C.F.R. § 314.53(f)(2)(i).

F. THE ORANGE BOOK LISTING FOR PROAIR® HFA AND COUNTERCLAIM-DEFENDANTS' REFUSAL TO COMPLY WITH THE FEDERAL TRADE COMMISSION'S DELISTING REQUEST

66. At the time Amneal NY and Amneal Ireland submitted Amneal's ANDA seeking FDA approval to market a generic version of ProAir® HFA, all five Asserted Patents were listed in the Orange Book for ProAir® HFA. Attached as Exhibit K is a copy of the Orange Book listing for ProAir® HFA.

67. At the time of filing this Answer, Affirmative Defenses, and Counterclaims, all five Asserted Patents remained listed in the Orange Book for ProAir®.

68. None of the Asserted Patents is properly listed in the Orange Book because all of the Asserted Patents claim devices, and none of the Asserted Patents claim a drug, drug substance (active ingredient), drug product (formulation or composition), or a method of using a drug, as required under 21 U.S.C. § 355(b)(1)(A)(viii).

69. The United States Federal Trade Commission (the "FTC") has determined that the Asserted Patents are not properly listed in the Orange Book for ProAir® HFA. On or about November 7, 2023, the FTC sent a letter (the "FTC Delisting Letter") to Counterclaim-Defendant Teva Branded informing Teva Branded that the FTC believes that all of the Asserted Patents (plus others) are "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents. A copy of the FTC Delisting Letter is attached hereto as Exhibit L.

70. The FTC Delisting Letter cites the FTC's September 14, 2023 statement concerning brand drug manufacturer's improper listing of patents in the Orange Book, which explains the FTC's position that patents, including the Asserted Patents, are not properly listed in the Orange Book, and that the improper listing of patents in the Orange Book "undermines the competitive process" and "may also constitute illegal monopolization . . . ."

71. In an interview published on November 12, 2023 in Citeline Regulatory's "Pink Sheet," (attached hereto as Exhibit M) Rahul Rao, the Deputy Director of the FTC's Bureau of Competition, explained why the FTC sent the FTC Delisting Letter to Teva Branded (among others):

> The Orange Book is only supposed to list patents covering active drug ingredients. So, we focused on device patents that have nothing to do with the active drug. Our staff analyzed several different types of these products and listings with an initial focus on products that were widely used and have been around for a while and we would have expected to see more generic competition. For example, asthma and COPD inhalers were a particular area of focus for us. Over 40 million Americans rely on inhalers and a lot of the drugs using these inhalers have been around for several decades. But we're still seeing people paying hundreds and hundreds of dollars for them.
>
> And we're not seeing a lot of lower cost generic use, even though the drugs have been around for several decades and have long expired drug substance patents. So that's what made inhalers like the asthma and COPD products a particular concern.
>
> * * * * *
>
> In the last few years, there's been a lot of discussion in this space on the Orange Book and how abusive listings can negatively affect competition and ultimately patients. So, we just thought more can be done here to help ensure that drug manufacturers don't abuse the Orange Book process.

72. The FTC further explained in that interview that the FTC wants Teva Branded to delist the Asserted Patents (among others):

> Q: What's your goal with the letters? Do you want companies to delist the patents? Is FTC looking to take enforcement action if they don't?
>
> Yes, we would like the companies to delist patents. We've just identified patents that we think are improperly listed and we have opted in these instances to go through the FDA process on how to address improper Orange Book listings, which involves delisting.

73. The FTC further explained in that interview that drug-device patents that do not claim the active ingredient should not be listed in the Orange Book:

> Q: …Does the FTC think that there are device patents that that can be listed or do you think that under the statute none of them can be listed?
>
> I don't think it's particularly controversial in terms of the statute, the regulations and the cases, and I think there have been FTC and FDA statements on this, that only patents that claim the active ingredient should be listed in the Orange Book. And drug-device patents that do not claim the active ingredient should not be listed.

74. The publication of that interview concludes with the following statement from the FTC:

> And ultimately, we think the law is actually relatively clear. There's not a lot of ambiguity here in terms of what should and should not be listed.

75. On information and belief, despite receiving the FTC's Delisting Letter and despite receiving notification from the FDA regarding the FTC's listing dispute regarding ProAir® HFA, none of the Counterclaim-Defendants has agreed to request that the FDA delist the Asserted Patents or requested the FDA delist the Asserted Patents.

76. None of the Asserted Patents satisfies any of the statutory requirements for being properly listed in the Orange Book.

77. None of the Asserted Patents claims a method of using a drug.

78. None of the Asserted Patents claims an approved method of using ProAir® HFA.

79. None of the Asserted Patents claims "the drug for which the applicant submitted" the ProAir® NDA.

80. None of the Asserted Patents is "a drug substance (active ingredient) patent" or claim a drug substance or active ingredient.

81. None of the Asserted Patents is "a drug product (formulation or composition) patent" or claim a drug product or drug formulation, or drug composition.

82. None of the Asserted Patents claims the active ingredient in ProAir® HFA.

83. None of the Asserted Patents claims a drug.

84. None of the Asserted Patents contains the phrase "albuterol sulfate," which is the name of the active ingredient in ProAir® HFA.

85. None of the Asserted Patents contains the word "albuterol."

86. In addition to being listed in the Orange Book for ProAir® HFA, each Asserted Patent is also concurrently listed in the Orange Book for at least one other product. Those other products include QVAR 40, QVAR 80, QVAR Redihaler, ProAir Digihaler, ProAir Respiclick, ArmonAir Digihaler, ArmonAir Respiclick, AirDuo Digihaler, and/or AirDuo Respiclick.

87. Attached as Exhibit N is a copy of the Orange Book listing for QVAR 40, which was approved under NDA No. 020911. The active ingredient in QVAR 40 is beclomethasone dipropionate.

88. Attached as Exhibit O is a copy of the Orange Book listing for QVAR 80, which was approved under NDA No. 020911. The active ingredient in QVAR 80 is beclomethasone dipropionate.

89. Attached as Exhibit P is a copy of the Orange Book listing for QVAR Redihaler, which was approved under NDA No 207921. The active ingredient in QVAR Redihaler is beclomethasone dipropionate.

90. Beclomethasone dipropionate is a different active ingredient than albuterol sulfate.

91. Attached as Exhibit Q is a copy of the Orange Book listing for ProAir Digihaler, which was approved under NDA No. 205636. The active ingredient in ProAir Digihaler is albuterol sulfate.

92. Attached as Exhibit R is a copy of the Orange Book listing for ProAir Respiclick, which was approved under NDA No. 205636. The active ingredient in ProAir Respiclick is albuterol sulfate.

93. Attached as Exhibit S is a copy of the Orange Book listing for ArmonAir Respiclick, which was approved under NDA No. 208798. The active ingredient in ArmonAir Respiclick is fluticasone propionate.

94. Attached as Exhibit T is a copy of the Orange Book listing for ArmonAir Digihaler, which was approved under NDA No. 208798. The active ingredient in ArmonAir Digihaler is fluticasone propionate.

95. Fluticasone propionate is a different active ingredient than albuterol sulfate.

96. Attached as Exhibit U is a copy of the Orange Book listing for AirDuo Digihaler, which was approved under NDA No. 208799. The active ingredients in AirDuo Digihaler are fluticasone propionate and salmeterol xinafoate.

97. Attached as Exhibit V is a copy of the Orange Book listing for AirDuo Respiclick, which was approved under NDA No. 208799. The active ingredients in AirDuo Respiclick are fluticasone propionate and salmeterol xinafoate.

98. Fluticasone propionate and salmeterol xinafoate are each a different active ingredient than albuterol sulfate.

99. The Orange Book listing of the Asserted Patents for other products shows a pattern and practice by Counterclaim-Defendants of improperly listing the Asserted Patents in the Orange Book for multiple products including ProAir® HFA to, among other things, deter generic market entry.

100. Counterclaim-Defendants' enforcement efforts against, for example, Perrigo and Lupin regarding Orange Book patents listed for ProAir® HFA further shows that Counterclaim-Defendants are using improperly-listed Orange Book patents to hinder and delay generic market entry.

G. COUNTERCLAIM-DEFENDANTS ABUSE ORANGE BOOK AND REGULATORY PROCESS BY PURSUING BASELESS PATENT LITIGATION

101. Because Counterclaim-Defendants had improperly listed the Asserted Patents in the Orange Book, Amneal NY and Amneal Ireland were required to submit Paragraph IV Certifications as to each of the Asserted Patents (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Asserted Patents. The Amneal Notice Letter, dated August 24, 2023, and, on information and belief, received by Counterclaim-Defendants on August 28, 2023, notified Counterclaim-Defendants that Amneal NY and Amneal Ireland had submitted to the FDA Amneal's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

102. In response, Counterclaim-Defendants filed this lawsuit under 35 U.S.C. § 271(e), alleging Amneal infringed the Asserted Patents. The lawsuit triggered the Hatch-Waxman Act's 30-month stay of final approval of Amneal's ANDA, which occurs only when an NDA holder files suit within 45 days of receiving notice of an ANDA with a Paragraph IV Certification. *See*

21 U.S.C. § 355(j)(5)(B)(iii). But for Counterclaim-Defendants' improper Orange Book listing, Amneal NY and Amneal Ireland would not have submitted Paragraph IV Certifications (but instead a Paragraph I Certification), and no 30-month stay would be imposed. Similarly, but for Counterclaim-Defendants' decision to file this baseless lawsuit within 45 days of receipt of the Amneal Notice Letter, no 30-month stay would be imposed.

103. Counterclaim-Defendants' patent infringement claims asserted in this lawsuit against Amneal are objectively baseless and were brought in bad faith. No reasonable litigant could expect to secure favorable relief against Amneal on the merits because Amneal's ANDA Product does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid.

104. Specifically, the Asserted Patents are directed to devices or portions of devices, and the device that Amneal seeks approval to use in Amneal's ANDA is itself prior art to the Asserted Patents. Thus, the Asserted Patents cannot cover the device used by Amneal under the doctrine of equivalents, because that would necessarily ensnare the prior art. And if the Amneal device is deemed to literally infringe the Asserted Patents, then axiomatically, the Asserted Patents would be invalid as anticipated.

105. Counterclaim-Defendants' patent litigation against Amneal as to the Asserted Patents constitutes sham litigation because the litigation was brought without any reasonable chance of prevailing and, on information and belief, for the specific and purpose of restricting competition by Amneal by delaying approval of Amneal's generic equivalent of ProAir® HFA.

H. MARKET POWER AND MARKET DEFINITION

106. At all relevant times, Counterclaim-Defendants had monopoly power in the market for ProAir® HFA and its generic equivalents because it had the power to raise or maintain the price of ProAir® HFA and/or an authorized generic version of ProAir® HFA

("ProAir® AG"), which Counterclaim-Defendants also marketed, at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable, as well as the power to exclude competitors.

107. At all times during Counterclaim-Defendants' monopoly, a small but significant, non-transitory increase to the price of ProAir® HFA and its generic equivalents would not have caused Counterclaim-Defendants to suffer a significant loss of sales.

108. On information and belief, ProAir® HFA and its generic equivalents do not exhibit significant, positive cross-elasticity of demand with respect to price with any other albuterol sulfate inhalant products. Notwithstanding the commercialization of other albuterol sulfate inhalant products, Counterclaim-Defendants continued to charge supracompetitive prices and exclude competitors.

109. On information and belief, Counterclaim-Defendants sold ProAir® HFA and the ProAir® AG at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

110. Counterclaim-Defendants have, and have exercised, the power to exclude competition to ProAir® HFA and its generic equivalents.

111. Counterclaim-Defendants enjoyed high barriers to entry with respect to the brand and generic versions of ProAir® HFA.

112. As set out above, Counterclaim-Defendants' anticompetitive conduct—including their improper listing of the Asserted Patents in the Orange Book and their filing of this sham litigation within 45 days of the receipt of Amneal's Notice Letter—is part of a pattern of conduct that began long before the instant litigation. Counterclaim-Defendants have, and have maintained, market power throughout the entirety of the course of their anticompetitive conduct.

113. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Counterclaim-Defendants' ability to control prices of its ProAir® HFA and ProAir® AG, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, among other things, (a) the fact that additional competing generic equivalents would have entered the market at substantial discounts to the brand version but for Counterclaim-Defendants' anticompetitive conduct; (b) Counterclaim-Defendants' history of improperly listing patents in the Orange Book and filing sham litigation with respect to the same; and (c) Counterclaim-Defendants' supracompetitive pricing for ProAir® HFA and ProAir® AG.

114. To the extent proof of monopoly power by defining a relevant product market is required, Amneal alleges that the relevant antitrust market is the market for ProAir® HFA and its generic equivalents. ProAir® HFA and its generic equivalents are not reasonably interchangeable with other products due to the distinct qualities and characteristics of ProAir® HFA, which distinguish it from other albuterol sulfate inhalants. Indeed, researchers have recognized significant differences across the spectrum of albuterol sulfate HFA inhalation aerosol products. Johnson et al., *The effect of a holding chamber on albuterol metered-dose inhaler product differences*, ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY 117(3):246-50 (2016). doi: 10.1016/j.anai.2016.07.016. PMID: 27613457 (attached as Exhibit W). Accordingly, ProAir® HFA and its generic equivalents are appropriately considered as a market of their own.

115. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

116. Thus, for purposes of this lawsuit, the market for the sale of ProAir® HFA and its generic equivalents in the United States (the "Relevant Market") constitutes a relevant market. In the alternative, the relevant market encompasses all albuterol sulfate HFA inhaler aerosol products (the "Alternative Relevant Market").[1]

117. Upon information and belief, at all relevant times Counterclaim Defendants had a predominant share of the Relevant Market.

118. On information and belief, Counterclaim-Defendants were able to set prices of ProAir® HFA and the ProAir® AG above that which would be charged in a competitive market.

119. Counterclaim-Defendants possess monopoly power in the Relevant Market, as evidenced by, among other factors, their prior pricing actions and dominant market share.

I. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

120. Amneal plans to launch the Amneal ANDA Products within days or weeks of receipt of final FDA approval.

121. Via a letter dated November 9, 2023, the FDA informed Amneal that it has set a goal date of June 25, 2024 for review of Amneal's ANDA if an inspection is not required, and a goal date of August 25, 2024 for review of Amneal's ANDA if an inspection is required. Attached as Exhibit X is a copy of the November 9, 2023 FDA letter. Amneal reasonably expects to receive FDA approval in the summer of 2024. Because of Counterclaim-Defendants anticompetitive conduct, that approval will be tentative, meaning that Amneal will need to wait until expiration of the 30-month stay to receive final approval and launch the Amneal ANDA

[1] Amneal maintains that the relevant product market for purposes of its Counterclaims is ProAir® HFA and its generic equivalents. However, to the extent the relevant product market is construed to encompass all albuterol sulfate HFA inhaler aerosol products (the Alternative Relevant Market), use of the term 'Relevant Market' herein encompasses both the Relevant Market and the Alternative Relevant Market.

Products. The approval in the summer of 2024 would be final but for Counterclaim-Defendants' anticompetitive conduct.

122. Amneal is making multi-million dollar investments to enable a successful launch as early as the summer of 2024. Specifically, in 2023 and early 2024, Amneal is making several million dollars in capital expenditures on new and expanded filling and packaging lines for the Amneal ANDA Products, as is spending several million dollars on device components, such as valves and actuators.

123. On information and belief, some of the device components that Amneal is purchasing will expire before expiration of the 30-month stay.

124. Counterclaim-Defendants' supracompetitive scheme to maintain its monopoly in the Relevant Market included delaying Amneal's entry through (1) Orange Book abuse and (2) engaging in sham litigation. Counterclaim-Defendants' anticompetitive scheme has had a direct, substantial, and adverse effect on Amneal and interstate competition in the Relevant Market by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the Relevant Market.

125. By impeding competition from generic equivalent products, including Amneal's, Counterclaim-Defendants' anticompetitive scheme has allowed (and, unless restrained by this Court, will continue to allow) Counterclaim-Defendants to maintain and extend their monopoly power in the Relevant Market and to sell ProAir® HFA and the ProAir® AG at artificially-inflated monopoly prices.

126. Counterclaim-Defendants' anticompetitive scheme has harmed the competitive process and has had a substantial effect on interstate commerce, as it has allowed Counterclaim Defendants to charge wholesalers, retailers, payors, and consumers nationwide supracompetitive

prices. But for this anticompetitive conduct, consumers and payors would have enjoyed the benefits of lower-priced generic competition from Amneal earlier. Instead, as a result of Counterclaim-Defendants' strategies, which include improper listing of the Asserted Patents in the Orange Book and engaging in sham litigation, consumers and payors have been forced to pay monopoly prices for Counterclaim-Defendants' ProAir® HFA and the ProAir® AG. The impact of Counterclaim-Defendants' anticompetitive conduct, and the accompanying supracompetitive pricing, is felt throughout the health care industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

127. Amneal has suffered, and will continue to suffer, harm as a result of Counterclaim-Defendants' anticompetitive conduct. That harm includes:

a. Loss of future sales and profits due to being foreclosed from selling in the Relevant Market;
b. The large amount of time and expense associated with having to fight baseless, sham patent litigation based on patents that were improperly listed in the Orange Book;
c. A delay in Amneal's ability to recoup its investment in filling and packaging lines and device components for the Amneal ANDA Products; and
d. The loss of Amneal's investment in device components that will expire before expiration of the 30-month stay resultant from Counterclaim-Defendants' improper listing of patents in the Orange Book.

128. A claimant satisfies the injury-in-fact requirement of standing where, as here, "the threatened injury is real, immediate, and direct." *See Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (quoting *Davis v. Fed. Election Com'n*, 554 U.S. 724, 734 (2008)).

129. "[T]he creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *See Pfizer Inc.*, 726 F. Supp 2d at 930 (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008)).

130. The injury to Amneal is immediate. Amneal is already spending time and money to litigate this baseless and sham patent litigation. Because Counterclaim-Defendants filed the instant patent suit, alleging infringement of patents improperly listed in the Orange Book, Amneal's final FDA approval is subject to the automatic 30-month stay. Based on the date which Counterclaim-Defendants filed the present lawsuit, Amneal's ANDA would not be eligible for final approval until February 28, 2026. Accordingly, from the date of Amneal's imminent tentative approval (in the summer of 2024) through February 28, 2026, 2026, Amneal's ANDA will be ineligible for final approval, and Amneal therefore will be deprived of the ability to launch its generic product, as a result of the Counterclaim-Defendants' anticompetitive conduct.

131. As a result of Counterclaim-Defendants' improper listing of the Asserted Patents and sham litigation, Amneal has already suffered and will imminently suffer the injuries outlined above.

132. Counterclaim-Defendants' anticompetitive conduct, as alleged herein, is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine or any statute of limitations.

133. There is and was no legitimate, procompetitive justification for Counterclaim-Defendants' conduct. Even if there was some conceivable and cognizable justification, Counterclaim-Defendants' conduct was not necessary to achieve such a purpose, and, in any event, any procompetitive effects would be outweighed by the scheme's anticompetitive effects on Amneal, competition, and consumers.

COUNT 1:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 8,132,712

134. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–133 of its Counterclaims, as if fully set forth herein.

135. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '712 patent from the Orange Book.

136. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '712 patent in the Orange Book.

137. The '712 patent is not properly listed in the Orange Book.

138. The '712 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

139. The '712 patent does not claim a method of using a drug.

140. The '712 patent does not claim an approved method of using ProAir® HFA.

141. The '712 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

142. The '712 patent is not "a drug substance (active ingredient) patent."

143. The '712 patent does not claim a drug substance.

144. The '712 patent does not claim an active ingredient.

145. The '712 patent is not "a drug product (formulation or composition) patent."

146. The '712 patent does not claim a drug product.

147. The '712 patent does not claim a drug formulation.

148. The '712 patent does not claim a drug composition.

149. The '712 patent does not claim a drug.

150. The FTC has already determined that the '712 patent is not properly listed in the Orange Book for ProAir® HFA.

151. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '712 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

152. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '712 patent.

153. The '712 patent contains 19 claims, of which only claims 1, 18, and 19 are independent. A copy of the '712 patent is attached as Exhibit A to the Complaint.

154. Claim 1 of the '712 patent is directed to "[a] dose counter for a metered-dose inhaler" having several recited structural features.

155. Claim 1 of the '712 patent recites as follows:

> A dose counter for a metered-dose inhaler, the counter comprising:
>
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
>
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
>
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

156. Claim 18 of the ’712 patent is directed to “[t]he use of a dose counter for preventing miscounting in a metered dose inhaler,” in which the dose counter has several recited structural features.

157. Claim 18 of the ’712 patent recites as follows:

> The use of a dose counter for preventing miscounting in a metered dose inhaler, the dose counter comprising:
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

158. Claim 19 of the ’712 patent is directed to “[t]he use of a dose counter for preventing undercounting in a metered dose inhaler,” in which the dose counter has several recited structural features.

159. Claim 19 of the ’712 patent recites as follows:

> The use of a dose counter for preventing undercounting in a metered dose inhaler, the dose counter comprising:
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;

> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

160. None of the claims of the ’712 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

161. None of the claims of the ’712 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

162. The ’712 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

163. Other than reciting the name of the assignee “Ivax Pharmaceuticals Ireland,” the ’712 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

164. In addition to being listed in the Orange Book entry for ProAir® HFA, the ’712 patent is listed in the Orange Book entry for QVAR Redihaler.

COUNT 2:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 9,463,289

165. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–164 of its Counterclaims, as if fully set forth herein.

166. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '289 patent from the Orange Book.

167. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '289 patent in the Orange Book.

168. The '289 patent is not properly listed in the Orange Book.

169. The '289 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

170. The '289 patent does not claim a method of using a drug.

171. The '289 patent does not claim an approved method of using ProAir® HFA.

172. The '289 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

173. The '289 patent is not "a drug substance (active ingredient) patent."

174. The '289 patent does not claim a drug substance.

175. The '289 patent does not claim an active ingredient.

176. The '289 patent is not "a drug product (formulation or composition) patent."

177. The '289 patent does not claim a drug product.

178. The '289 patent does not claim a drug formulation.

179. The '289 patent does not claim a drug composition.

180. The '289 patent does not claim a drug.

181. The FTC has already determined that the '289 patent is not properly listed in the Orange Book for ProAir® HFA.

182. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '289 patent is "improperly

or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

183. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '289 patent.

184. The '289 patent contains 10 claims, of which only claim 1 is independent. A copy of the '289 patent is attached as Exhibit B to the Complaint.

185. Claim 1 of the '289 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

186. None of the claims of the '289 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

187. None of the claims of the ’289 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

188. The ’289 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

189. Other than reciting the name of the assignees and applicants “Ivax Pharmaceuticals Ireland,” and “Teva Pharmaceuticals Ireland,” the ’289 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

190. In addition to being listed in the Orange Book entry for ProAir® HFA, the ’289 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

COUNT 3:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 9,808,587

191. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–190 of its Counterclaims, as if fully set forth herein.

192. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the ’587 patent from the Orange Book.

193. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the ’587 patent in the Orange Book.

194. The ’587 patent is not properly listed in the Orange Book.

195. The ’587 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

196. The ’587 patent does not claim a method of using a drug.

197. The ’587 patent does not claim an approved method of using ProAir® HFA.

198. The ’587 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

199. The ’587 patent is not “a drug substance (active ingredient) patent.”

200. The ’587 patent does not claim a drug substance.

201. The ’587 patent does not claim an active ingredient.

202. The ’587 patent is not “a drug product (formulation or composition) patent.”

203. The ’587 patent does not claim a drug product.

204. The ’587 patent does not claim a drug formulation.

205. The ’587 patent does not claim a drug composition.

206. The ’587 patent does not claim a drug.

207. The FTC has already determined that the ’587 patent is not properly listed in the Orange Book for ProAir® HFA.

208. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’587 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

209. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all five Asserted Patents, including the ’587 patent.

210. The ’587 patent contains 22 claims, of which only claims 1, 12, and 13 are independent. A copy of the ’587 patent is attached as Exhibit C to the Complaint.

211. Claim 1 of the ’587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

212. Claim 12 of the ’587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

213. Claim 13 of the ’587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

214. None of the claims of the ’587 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

215. None of the claims of the ’587 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

216. The ’587 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

217. Other than reciting the name of the assignees and applicants “Ivax Pharmaceuticals Ireland,” and “Teva Pharmaceuticals Ireland,” the ’587 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

218. In addition to being listed in the Orange Book entry for ProAir® HFA, the '587 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

COUNT 4:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 10,561,808

219. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–218 of its Counterclaims, as if fully set forth herein.

220. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '808 patent from the Orange Book.

221. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '808 patent in the Orange Book.

222. The '808 patent is not properly listed in the Orange Book.

223. The '808 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

224. The '808 patent does not claim a method of using a drug.

225. The '808 patent does not claim an approved method of using ProAir® HFA.

226. The '808 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

227. The '808 patent is not "a drug substance (active ingredient) patent."

228. The '808 patent does not claim a drug substance.

229. The '808 patent does not claim an active ingredient.

230. The '808 patent is not "a drug product (formulation or composition) patent."

231. The '808 patent does not claim a drug product.

232. The '808 patent does not claim a drug formulation.

233. The ’808 patent does not claim a drug composition.

234. The ’808 patent does not claim a drug.

235. The FTC has already determined that the ’808 patent is not properly listed in the Orange Book for ProAir® HFA.

236. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’808 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

237. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all five Asserted Patents, including the ’808 patent.

238. The ’808 patent contains 29 claims, of which only claim 1 is independent. A copy of the ’808 patent is attached as Exhibit D to the Complaint.

239. Claim 1 of the ’808 patent recites:

> A dose counter for an inhaler, the dose counter having
> a counter display arranged to indicate dosage information,
> a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,
> wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

240. None of the claims of the ’808 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active

pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

241. None of the claims of the '808 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

242. The '808 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

243. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '808 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

244. In addition to being listed in the Orange Book entry for ProAir® HFA, the '808 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) AirDuo Digihaler, (3) AirDuo Respiclick, (4) ArmonAir Digihaler, (5) ArmonAir Respiclick, (6) ProAir Digihaler, (7) ProAir Respiclick, (8) QVAR40, and (9) QVAR80.

COUNT 5:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 11,395,889

245. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–244 of its Counterclaims, as if fully set forth herein.

246. Amneal hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '889 patent from the Orange Book.

247. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '889 patent in the Orange Book.

248. The ’889 patent is not properly listed in the Orange Book.

249. The ’889 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

250. The ’889 patent does not claim a method of using a drug.

251. The ’889 patent does not claim an approved method of using ProAir® HFA.

252. The ’889 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

253. The ’889 patent is not “a drug substance (active ingredient) patent.”

254. The ’889 patent does not claim a drug substance.

255. The ’889 patent does not claim an active ingredient.

256. The ’889 patent is not “a drug product (formulation or composition) patent.”

257. The ’889 patent does not claim a drug product.

258. The ’889 patent does not claim a drug formulation.

259. The ’889 patent does not claim a drug composition.

260. The ’889 patent does not claim a drug.

261. The FTC has already determined that the ’889 patent is not properly listed in the Orange Book for ProAir® HFA.

262. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’889 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

263. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '889 patent.

264. The '889 patent contains 6 claims, of which only claim 1 is independent. A copy of the '889 patent is attached as Exhibit E to the Complaint.

265. Claim 1 of the '889 patent recites:

> An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body,
>
> an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and
>
> wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

266. None of the claims of the '889 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

267. None of the claims of the '889 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

268. The '889 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

269. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '889 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

270. In addition to being listed in the Orange Book entry for ProAir® HFA, the '889 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 6:
UNLAWFUL MONOPOLIZATION – OVERALL SCHEME
IN VIOLATION OF THE SHERMAN ACT

271. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–270 of its Counterclaims, as if fully set forth herein.

272. This claim arises under the Sherman Act, 15 U.S.C. § 2 and under the Clayton Act, 15 U.S.C. §§ 15 and 26.

273. Counterclaim-Defendants are engaged in the development, commercialization, and marketing of prescription pharmaceutical products for the treatment of various disorders.

274. Amneal is a supplier of generic pharmaceutical products.

275. Amneal is a potential future direct competitor with Counterclaim-Defendants in the Relevant Market.

276. On information and belief, Counterclaim-Defendants have a predominant share of the Relevant Market.

277. Counterclaim-Defendants have monopoly power in the Relevant Market.

278. Counterclaim-Defendants have exercised monopoly power in the Relevant Market.

279. Counterclaim-Defendants have the power to control prices and/or exclude competition in, or prevent entry into, the Relevant Market.

280. Substantial barriers to entry into the Relevant Market exist, including but not limited to, regulatory requirements and Counterclaim-Defendants' actions to delay and preclude entry into the Relevant Market, including but not limited to, improperly listing the Asserted Patents in the Orange Book and refusing to delist them, Counterclaim-Defendants' history of enforcement efforts relating to patents listed in the Orange Book for ProAir® HFA, and Counterclaim-Defendants' present lawsuit for infringement of the Asserted Patents.

281. Counterclaim-Defendants knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of the Amneal ANDA Products. Counterclaim-Defendants have baselessly and improperly wielded the Asserted Patents, including by improperly listing them in the Orange Book and asserting them in this case and others to trigger the automatic 30-month stay of FDA approval of ANDAs seeking approval to market generic versions of ProAir® HFA.

282. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

283. Counterclaim-Defendants engaged in this anticompetitive scheme and each lawsuit in order to consolidate, entrench, and enhance their monopolistic position in the Relevant

Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

284. Counterclaim-Defendants' scheme and actions have no procompetitive, business justification.

285. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Amneal are objectively baseless. No reasonable litigant could expect to secure favorable relief against Amneal on the merits because Amneal's ANDA Product does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid. The Asserted Patents are directed to devices or portions of devices, and the device that Amneal seeks approval to use in its ANDA is itself prior art to the Asserted Patents. Thus, the Asserted Patents cannot cover the device used by Amneal under the doctrine of equivalents, because that would necessarily ensnare the prior art. And if the Amneal device is deemed to literally infringe Asserted Patents, then axiomatically, the Asserted Patents would be invalid as anticipated.

286. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Amneal are also objectively baseless because the Court does not properly have subject matter jurisdiction over this case.

287. Counterclaim-Defendants brought their patent infringement claims in bad faith, for an improper purpose, as a means of directly interfering with and harming Amneal's business, and to forestall, frustrate, and prevent competition by Amneal.

288. Counterclaim-Defendants intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the Relevant Market. Counterclaim-Defendants' lawsuit filed against Amneal alleging infringement

of the Asserted Patents is both objectively and subjectively baseless, and constitutes sham litigation and bad faith enforcement of the Asserted Patents.

289. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

290. But for Counterclaim-Defendants' actions alleged herein, Counterclaim-Defendants' market share in the Relevant Market would have decreased with the addition of Amneal in the Relevant Market, to the benefit of competition and consumers in the Relevant Market.

291. On information and belief, Counterclaim-Defendants have not acted to advance their position by competing on the merits in the Relevant Market, but solely to exclude potential competition from an alternate source in the Relevant Market.

292. The effects of Counterclaim-Defendants' overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the Relevant Market, and permit Counterclaim-Defendants to monopolize the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, including the following effects, among others:

a. A delay of competition in the manufacture and sale of a generic equivalent of ProAir® HFA;

b. Purchasers of albuterol inhalants will be deprived of the benefits of free and open competition;

c. Payers and consumers will pay supracompetitive prices for albuterol inhalants;

d. Amneal will be deprived of revenues and profits it otherwise would have achieved but for Counterclaim-Defendants' illegal conduct.

293. Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful activities threaten loss or damage to Amneal by forestalling, frustrating, and preventing Amneal's ability to compete in the Relevant Market.

294. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

295. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

296. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

297. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 7:
UNLAWFUL MONOPOLIZATION – SHAM LITIGATION
IN VIOLATION OF THE SHERMAN ACT

298. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–297 of its Counterclaims, as if fully set forth herein.

299. Counterclaim-Defendants' have monopoly power in the Relevant Market.

300. Counterclaim-Defendants' knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Amneal's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant

Market through, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate their monopoly over sales of albuterol inhalers in the United States.

301. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

302. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

303. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

304. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

305. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

306. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

307. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 8:
UNLAWFUL MONOPOLIZATION – IMPROPER ORANGE BOOK LISTING IN VIOLATION OF THE SHERMAN ACT

308. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–307 of its Counterclaims, as if fully set forth herein.

309. Counterclaim-Defendants' have monopoly power in the Relevant Market.

310. Counterclaim-Defendants' knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Amneal's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, improperly listing the Asserted Patents in the Orange Book.

311. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

312. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

313. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

314. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

315. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

316. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 9:
ATTEMPTED UNLAWFUL MONOPOLIZATION
IN VIOLATION OF THE SHERMAN ACT

317. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–316 of its Counterclaim, as if fully set forth herein.

318. Counterclaim-Defendants' scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the market for albuterol sulfate inhalants in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On information and belief, Counterclaim-Defendants purposefully and knowingly improperly listed the Asserted Patents, and others, in the Orange Book, and refused to delist them, even after receiving a letter from the FTC stating that they should be delisted. Counterclaim-Defendants then commenced sham patent litigation against Amneal under 35 U.S.C. § 271(e), despite fully knowing the Asserted Patents were improperly listed in the Orange Book, thereby unlawfully procuring an automatic 30-month stay of FDA approval.

319. Counterclaim-Defendants have created a dangerous probability that they will achieve their goal of monopolizing the Relevant Market. Counterclaim-Defendants' market share in the Relevant Market, coupled with other market structure and conduct evidence, including but

not limited to, the lack of competition in the Relevant Market, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and the related economic and market factors, constitute a dangerous probability that Counterclaim-Defendants will succeed in their efforts to maintain a monopoly in the Relevant Market.

COUNT 10:
SHAM LITIGATION – MONOPOLIZATION
N.J. STAT, ANN. §§ 56:9-1 ET SEQ.

320. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–319 of its Counterclaims, as if fully set forth herein.

321. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. 56:9 et seq., and seeks a judgment that Counterclaim Defendants' conduct as alleged herein has violated New Jersey Antitrust, N.J. Stat. Ann. 56:9-4. Counterclaim-Defendants' conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. 56:9-4.

322. Specifically, Counterclaim-Defendants' anticompetitive scheme, including abuse of the regulatory processes and court filings and improperly listing the Asserted Patents in the Orange Book and refusing to delist them were calculated to maintain monopoly power in the Relevant Market, in violation of N.J. Stat. Ann. 56:9-4.

323. Counterclaim-Defendants' anticompetitive and exclusionary conduct has directly and proximately caused injury to Amneal's business and property, as set forth above. Amneal's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

COUNT 11:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT

324. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–323 of its Counterclaims, as if fully set forth herein.

325. Amneal does not, has not, and would not, if the products described in ANDA No. 211600 are marketed, directly or indirectly infringe any valid and enforceable claims of the '712, '289, '587, '808, and '889 patents, either literally or under the doctrine of equivalents.

326. Amneal's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Amneal ANDA Products will not infringe, directly or indirectly, any valid and enforceable claims of the '712, '289, '587, '808, and '889 patents, either literally or under the doctrine of equivalents.

327. Because Amneal has not infringed and will not infringe any valid and enforceable claim of the '712, '289, '587, '808, and '889 patents, Amneal is entitled to a declaratory judgment of non-infringement.

COUNT 12:
DECLARATORY JUDGMENT OF INVALIDITY

328. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–327 of its Counterclaims, as if fully set forth herein.

329. The claims of the '712, '289, '587, '808, and '889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112.

330. Because the claims of the '712, '289, '587, '808, and '889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, Amneal is entitled to a declaratory judgment of invalidity.

JURY DEMAND

Amneal demands a trial by jury on all issues for which a trial by jury is available under applicable law.

AMNEAL'S PRAYER FOR RELIEF

WHEREFORE, Amneal respectfully requests that the Court enter judgment in its favor and grant the following relief:

A. Declare that each of the Asserted Patents were not and are not properly listed in the Orange Book for ProAir® HFA.

B. Enter an Order requiring the holder of the ProAir® NDA to withdraw all of the Asserted Patents from the Orange Book listing for the ProAir® NDA, and to submit to the FDA an amendment to that effect to the ProAir® NDA, in compliance with 21 C.F.R. § 314.53(f)(2)(i).

C. Declare and enter judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2;

D. Enter judgment awarding treble damages to Amneal under Section 4 of the Clayton Act, 15 U.S.C. § 15, for the damages sustained by Amneal as a result of Counterclaim-Defendants' unlawful conduct.

E. Enter an order permanently enjoining Counterclaim-Defendants from continuing the unlawful conduct alleged, and from engaging in related conduct in the future, including from monopolizing or attempting to monopolize the relevant product and geographic markets, as provided by 15 U.S.C. § 26;

F. Declare and enter judgment that Counterclaim-Defendants have violated N.J. Stat. Ann. §§ 56:9-1 Et Seq., and award Amneal damages, including costs and reasonable

attorneys' fees, sustained by Amneal as a result of Counterclaim-Defendants' unlawful conduct.

G. Enter judgment dismissing Counterclaim-Defendants' First Amended Complaint and denying each and every prayer for relief contained therein, with prejudice;

H. Declare and enter judgment that Amneal has not infringed any valid and enforceable claim of the Asserted Patents;

I. Declare and enter judgment that the Amneal ANDA Products and the submission of ANDA No. 211600 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Asserted Patents do not and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claims of the Asserted Patents;

J. Declare and enter judgment that the claims of the Asserted Patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, 112, and/or for obviousness-type double patenting.

K. Declare and enter judgment that this is an exceptional case under 35 U.S.C. § 285 and award Amneal its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

L. Award Amneal such other and further relief as the Court deems just and proper.

Dated: December 1, 2023 Respectfully submitted,

/s/ Rebekah Conroy

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Attorneys for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants/Counterclaim-Plaintiffs, by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding known at this time.

Dated: December 1, 2023

Respectfully submitted,

/s/ Rebekah Conroy

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Attorneys for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaim Plaintiffs by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: December 1, 2023

Respectfully submitted,

/s/ Rebekah Conroy

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